K123187

FEB 2 2 2013

510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person:	Karen Jones, Senior Manager, Regulatory Affairs 12050 Lone Peak Pkwy Draper, UT 84020 (801) 565-6231
Date Prepared:	October 10, 2012
Trade Name:	Edwards Lifesciences® Retrograde Cardioplegia Catheters with and without Duraflo Coating
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass, 21 CFR Part 870.4210, Product Code DWF, Class II
Predicate Device:	**K880103** – Retrograde Coronary Sinus Cardioplegia Cannulae **K991170** – Retrograde Cardioplegia Cannulae with Duraflo Treatment **K001565** – Steerable Retrograde Cardioplegia Cannula with and without Duraflo Treatment

Device Description:

Edwards Retrograde Coronary Sinus Cardioplegia Catheters (or Retrograde Cardioplegia Cannulae) are sterile, non-pyrogenic, single-use catheters made of flexible and non-flexible polymeric materials. They are intended to provide retrograde cardioplegia to the coronary sinus during cardiopulmonary bypass procedures.

Retrograde Cardioplegia Catheters have two or three lumens. One lumen delivers cardioplegia. A second lumen monitors pressure within the coronary sinus. If a third lumen is present, it either facilitates a manually inflated balloon or a stiffening wire.

Catheters include manually inflating or self-inflating smooth or textured occlusion balloons. A curved semi-rigid or malleable insertion stylet is provided with each catheter.

Edwards Retrograde Cardioplegia Catheters are also available with Duraflo™ (heparin) coating.

Indications for Use:

Retrograde coronary sinus cardioplegia catheters with and without Duraflo coating are intended for delivery of blood or cardioplegia solution intraoperatively to avoid cardiac damage and aid in myocardial protection.

Retrograde coronary sinus cardioplegia catheters may be used in pediatric or adult populations based on individual patient anatomy.

This device is for short-term use only (≤ 6 hours)

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Comparative Analysis:

The Retrograde Cardioplegia Catheters have the same fundamental scientific technology and principles of operation as the predicate devices. Minor differences in features relate to customer reference rather than the clinical performance of the device. The product range of sizes now includes 9 to 14 French, 8 to 12.5 inches in length, and balloons from 9mm to 3cm. Size variations relate directly to patient anatomy. Balloons have a smooth or textured surface, and can either be self inflating or manually inflating. Additionally, the polymeric material formulations in the devices have evolved, but material types remain the same as those originally cleared in predicate submissions.

Non Clinical Testing:

Bench and laboratory testing was performed and assures that the product meets its specifications per the table below. The performance testing met the acceptance criteria.

Testing	Criteria
Sterility	Per ISO11135-1, Sterilization of health care products – Ethylene oxide - Part 1:
Ethylene oxide sterilization residuals	ISO 10993-7, Biological evaluation of medical devices - Part 7:
Biocompatibility	Per ISO 10993-1 for External communicating device, direct circulating blood path, duration ≤ 24 hours.
Conical Fittings	Fittings must be compatible with standard connections.
Wire Encapsulation	Cannula body wire reinforcement shall be fully encapsulated.
Assembly Leak	Pressure drop must meet minimum requirement.
Kink	The cannulae shall not kink at a pre determined diameter.
Balloon Burst	Minimum pressures, diameter, and volume at burst must be maintained.
Balloon Leak	Balloon must not leak when inflated with pre determined volumes.
Pressure Monitoring	Flow testing will confirm patency of the pressure monitoring lumen.
Corrosion	The metallic components shall show no signs of corrosion.
Tensile	Confirmation of the bond strength of the catheter assembly must meet pre determined loads.

The Retrograde Cardioplegia Catheters conform to the following standards:

- ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing.
- ISO 10993-7, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO11135-1, Sterilization of health care products – Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO14971, Medical devices – Application of risk management to medical devices

Clinical Assessment:

A clinical assessment based on published studies was provided to support the pediatric indication.

Conclusion:

The Retrograde Cardioplegia Catheters are substantially equivalent to the cited predicate devices. The nonclinical tests and clinical assessment demonstrate that the devices are as safe and as effective as the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Edwards Lifesciences LLC
Karen Jones, Senior Principal Project Manager
12050 Lone Peak Pkwy.
Draper, UT 84020

Re: K123187
Trade/Device Name: Retrograde Cardioplegia Catheter
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: January 25, 2013
Received: January 28, 2013

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K123187

Device Name: Edwards Lifesciences® Retrograde Cardioplegia Catheter

Indications for Use:

Retrograde coronary sinus cardioplegia catheters with and without Duraflo coating are intended for delivery of blood or cardioplegia solution intraoperatively to avoid cardiac damage and aid in myocardial protection.

Retrograde coronary sinus cardioplegia catheters may be used in pediatric or adult populations based on the requirements of individual patient anatomy.

This device is for short-term use only (≤ 6 hours).

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Prescription Use ___x___ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Matthew G. Hillebrenner